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Dated: August 18, 2004

Signature: \_\_\_\_\_

*Shawn P. Foley*  
(Shawn P. Foley)

Docket No.:  
CELLTH 3.0-003 CONT CONT XII  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Warrell et al.

Application No.: 10/759,314

Group Art Unit: 1616

Filed: January 16, 2004

Examiner: A. N. Pryor

For: PROCESS FOR PRODUCING ARSENIC  
TRIOXIDE FORMULATIONS AND  
METHODS FOR TREATING CANCER USING  
ARSENIC TRIOXIDE OR MELASOPROL

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**REQUEST FOR CONSIDERATION OF INFORMATION UNDER 37 CFR § 1.97 (C)**

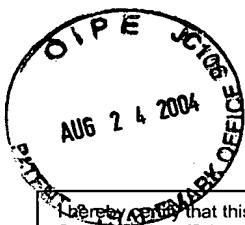
Dear Sir:

It is respectfully requested that the references cited in the enclosed form be considered pursuant to 37 C.F.R. § 1.97(c). Please charge Deposit Account No. 12-1095 in the amount of \$180.00 pursuant to 37 C.F.R. § 1.17(p). In the event that any additional fee is due in connection with the present request, the same should be charged to our Deposit Account No. 12-1095.

Dated: August 18, 2004

Respectfully submitted,

By *Shawn P. Foley*  
Shawn P. Foley  
Registration No.: 33,071  
LERNER, DAVID, LITTENBERG,  
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**INFORMATION DISCLOSURE STATEMENT**

Dear Sir:

It is respectfully requested that the references listed on the enclosed form be made of record and considered with respect to the above-referenced U.S. patent application. A copy of each reference was of record in United States Patent 6,723,351, the benefit of which is claimed under §120. Submission of the present Information Disclosure Statement should not be taken as an admission that the cited references are legally available prior art or that the same are pertinent or material.

In the event that any fee is due in connection with the present Information Disclosure Statement, the Commissioner is hereby authorized to charge the same to our Deposit Account

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Application No.: 10/759,314

Docket No.: CELLTH 3.0-003 CONT CONT XII

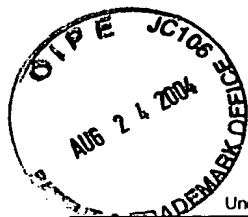
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				Filing Date	January 16, 2004
				First Named Inventor	Raymond P. Warrell, Jr.
				Art Unit	1616
				Examiner Name	A. N. Pryor
Sheet	1	of	5	Attorney Docket Number	CELLTH 3.0-003 CONT CONT XII

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	AA**	US-132,275-B1	10-15-1872	Gettings	
	AB**	US-232,807	10-05-1886	Dennett	
	AC**	US-3,700,498	10-24-1972	Kanazawa et al.	
	AD**	US-4,497,780	02-05-1985	Barin et al.	
	AE**	US-5,759,837	06-02-1998	Kuhajda et al.	
	AF**	US-2002/0183385	12-05-2002	Ellison et al.	
	AG**	US-6,720,011	04-13-2004	Zhang, Ting-Dong	
	AH**	US-6,770,304	08-03-2004	Warrell et al.	
	AI**	US-2003/0099719	05/2003	Warrell et al.	
	AJ**	US-6,723,351	04-20-2004	Warrell et al.	
	AK**	US-6,773,792	05-11-2004	Lu	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	BA	JP-51-88620	03-08-1976			
	BB	WO-95/01789	01-19-1995			
	BC	CN-1133725	10-23-1996			
	BD	CN-1131037	09-18-1996			
	BE	CN-1122700	05-22-1996			
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	BG	CN-1119113	03-27-1996			
	BH	CN-1061908	06-17-1992			
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	BJ	CN-1079391	12-15-1993			
	BK	WO-94/02103	02-03-1994			
	BL	FR-2 539 993	03-31-1994			
	BM	DE-43 17 331	12-01-1994			
	BN	WO-95/22336	08-24-1995			
	BO	LV-11667	06-20-1997			
	BP	WO-94/02108	02-03-1994			

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \*\*CITE NO.: Those patent(s) or publication(s) which are marked with an double asterisk (\*\*) next to the Cite No. are not supplied because they were previously cited by or submitted to the Office in a prior application relied upon in this application for an earlier filing date under 35 U.S.C. 120. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	CA	CUTLER et al., Article IV, American Journal of the Medical Sciences, pp. 74-84, January 1878	
	CB	FORKNER et al., "Arsenic as a therapeutic agent in chronic myelogenous leukemia", Jour.	

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				Art Unit	1616
				Examiner Name	A. N. Pryor
Sheet	2	of	5	Attorney Docket Number	CELLTH 3.0-003 CONT CONT XII

		A.M.A. 97(1):3-5, 1931	
CC	STEPHENS, et al., "The therapeutic effect of solution of potassium arsenite in chronic myelogenous leukemia", University of Rochester, pp. 1488-1502, 1936		
CD	NEUBAUER, "Arsenical cancer: a review", Arsenic Committee of the Medical Research Council, pp. 192-251, 1947		
CE	SHIBUYA, "Studies on experimental arsenious acid poisoning", Tokyo Jikeikai Ika Daigaku Zasshi, 86(4):653-675, 1971		
CF	PORIES et al., "Trace elements that act to inhibit neoplastic growth", Annals of New York Academy of Sciences, 199:265-273, June 25, 1972		
CG	MONFARDINI et al., "Survival in chronic myelogenous leukemia: influence of treatment and extent of disease at diagnosis", Cancer 31: 492-501, 1973		
CH	KERKVLIT et al., "Immunotoxicology Studies of Sodium Arsenate-effects of Exposure on Tumor Growth and Cell-mediated Tumor Immunity", J. Environmental, Vol. 4, pp. 65-79, 1980.		
CI	ISHINISHI, et al., "Study on Chronic Toxicity of Arsenic Trioxide in Rats with Special Reference to the Liver Damages", Fukuoka Acta Medicine, 71:27, 1980		
CJ	Arsenic, Environmental Health Criteria, 18, Geneva: WHO, 1981		
CK	CUZICK et al., "Medicinal Arsenic and Internal Malignancies", Br. J. Cancer, 45:904-911, 1982		
CL	QI and BI, "Method for Removing As <sub>2</sub> O <sub>3</sub> from Realgar, Chung Yao Tung Pao, 8(5):21-22, 1983		
CM	KASPER et al., "Hepatic Angiosarcoma and Bronchioloalveolar Carcinoma Induced by Fowler's Solution", JAMA 252(24):3407-3408, 1984		
CN	ZHANG et al., "Clinical Study on the Treatment of Acute Promyelocytic Leukemia with Ai Ling #1", J. of Traditional Chinese and Western Medicine, Vol. 4, No. 1, p. 19, 1984.		
CO	PERSHAGEN et al., "On the Pulmonary Tumorigenicity of Arsenic Trisulfide and Calcium Arsenate in Hamsters", Cancer Letters, 27:99-104, 1985		
CP	SHIMOTSUURA et al., "Studies on the Antineoplastic Actions of As <sub>2</sub> O <sub>3</sub> ", Shikwa Gakuho, 86:1237-1253, 1986		
CQ	YAMAMOTO et al., "Tumorigenicity of Inorganic Arsenic Compounds Following Intratracheal Instillations to the Lungs of Hamsters", Int. J. Cancer 40:220-223, 1987		
CR	LEE et al., "Induction of Gene Amplification by Arsenic", Science, 241: 79-81, 1988		
CS	LI et al., "Traditional Chinese and Western Medicine in the Treatment of 27 Patients with Malignant Lymphoma", Chinese J. Oncology, 10:61-62, 1988		
CT	SUN, HONGDE et al., "32 Cases of Acute Early Granulocytic Leukemia Treated with Ai-Ling No. 1 in Combination with Chinese Medical Practice of Pattern Identification", Zhongguo Zhongxiyi Jiehe Zazhi, Vol. 12(3), 170-171, 1992		
CU	PENG, ZHANG et al., "Treatment of Acute Promyelocyte Leukemia with Intravenous Arsenic Trioxide", Chinese Journal of Hematology, Vol. 17, Translation, February 1996		
CV	Arsen (III)-Sulfid As <sub>2</sub> S <sub>2</sub> ", Gmelin's Arsenic, 8.sup.th Edition, 17:422-433, 1952		
CW	Diarsendisulfid As <sub>2</sub> S <sub>2</sub> ", Gmelin's Arsenic, 8.sup.th Edition, 17:417-422, 1952		
CX	Goodman & Gilman's "The Pharmacological Basis of Therapeutics", Ninth Edition, McGraw-Hill, Health Professions Division, pp. 1659-1662		
CY	"Inorganic Arsenic Compounds Other Than Arsenic Health and Safety Guide", Health and Safety Guide No. 70, WHO, Geneva 1992		
CZ	"Xionghuang, Realgar", Chinese Pharmacopoeia (I), Guangdong Science and Technology Publishing House, China, pp. 298-299, 1995		
CA1	AKAO et al., "Arsenic Induces Apoptosis in B-cell Leukemic Cell Lines in Vitro: Activation of Caspases and Down-regulation of Bcl-2 Protein", British J of Hematology, 102, 1055-1060, 1998 ©Blackwell Science Ltd.		
CB1	ANDRE et al., "The PML and PML/RAR $\alpha$ Domains: From Autoimmunity to Molecular Oncology and From Retinoic Acid to Arsenic", Experimental Cell Research, 229:253-260, 1996 ©Academic Press, Inc. 1996		
CC1	Chemical Abstract, 63-Pharmaceuticals 11:317, 111:219272j and 111:219276p, 1987-1991		

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		Art Unit	1616		
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Sheet	3	of	5	Attorney Docket Number	CELLTH 3.0-003 CONT CONT XII

CD1	CHEN et al., "In Vitro Studies on Cellular and Molecular Mechanisms of Arsenic Trioxide (As <sub>2</sub> O <sub>3</sub> ) in the Treatment of Acute Promyelocytic Leukemia: As <sub>2</sub> O <sub>3</sub> induces NB <sub>4</sub> Cell Apoptosis with Down Regulation of Bcl-2 Expression and Modulation of PML-RAR $\alpha$ /PML proteins", Blood 88(3): 1052-1061, Aug. 1996. ©American Society of Hematology 1996
CE1	CHEN et al., "Use of Arsenic Trioxide (As <sub>2</sub> O <sub>3</sub> ) in the Treatment of Acute Promyelocytic Leukemia (APL):I. As <sub>2</sub> O <sub>3</sub> Exerts Dose-Dependent Dual Effects on APL Cells", Blood 89(9):3345-3353, 1997 ©The American Society of Hematology 1997
CF1	CHUNG et al., "Influence for Carcinoma Cell and Lymphatic Cell of Acetyl Arsonate", Yakhak Hoeji 40(5):599-607, 1996 (Abstract Only)
CG1	DE THE "L'oxyde d'arsenic: apres l'acide retinoique, un nouveau traitement cible dela leucemie aigue promyelocyttaire" Medecine/Sciences, 13:867-71, 1997
CH1	Dictionary of Inorganic Compounds, vol. 1, Ac-C <sub>10</sub> , IC-0006667-IC-000671 (1992)
CI1	FLAMIGNI et al., "Effect of Sodium Arsenite on the Induction and Turnover of Ornithine Decarboxylase Activity in Erythroleukemia Cells", Cell Biochemistry and Function 7:213-217, 1989
CJ1	Fluka, 1995/96 Catalog: 152-153
CK1	GERMOLEC et al., "Arsenic Induces Overexpression of Growth Factors in Human Keratinocytes", Toxicology and Applied Pharmacology, 141:301-318, 1996 ©Academic Press, Inc., 1996
CL1	HUANG et al., 1995, "The Clinical Study of QINGDAI Tablet for Treating Acute Promyelocytic Leukemia", China Magazine of Hematology, 16(1):26
CM1	KONIG et al., "Comparative Activity of Melarsoprol and Arsenic Trioxide in Chronic B-Cell Leukemia Lines", Blood 90(2):562-570, 1997. ©The American Society of Hematology 1997
CN1	KWONG et al., "Delicious Poison: Arsenic Trioxide for the Treatment of Leukemia", Blood 89:3487-8, 1997
CO1	LU et al., "Effective treatment of AML-M3 (APL) and Their Remission Maintenance with Realgar: A Pilot Clinical and Laboratory Study on 38 Patients", Blood, 90 (10 Suppl. 1, part 1):416A, #1849, 1997
CP1	LU et al., "Study of Reaglar in the Treatment of Acute Promyelocytic Leukemia (APL)-a pilot clinical and laboratory study on 32 Patients", China-Korea Medical Conference '97, 1997
CQ1	MERVIS, "Ancient Remedy Performs New Tricks", Science 273:578, 1996
CR1	NEUBAUER, "Arsenic Cancer: A Review", Arsenical Cancer, Arsenic Committee of the Medical Research Council, pp. 192-251, 1947
CS1	REICHL et al., "Effect of Arsenic on Cellular Metabolism after Single or Repeated Injection in Guinea Pigs", Arch. Toxicol, Suppl. 13, p. 363-65, 1989
CT1	Remington's Pharmaceutical Sciences, Mack Publishing Co., Easton, PA, pp. 1570-1580, 1990
CU1	SCHENK, Handbook of Preparative Inorganic Chemistry, 1:603, G. Brauer, Ed., Academic Press, New York, 2.sup.nd Edition, 1963
CV1	SHEN et al., "Use of Arsenic Trioxide (As <sub>2</sub> O <sub>3</sub> ) in the Treatment of Acute Promyelocytic Leukemia (APL):II Clinical Efficacy and Pharmacokinetics in Relapsed Patients", Blood 89(9):3354-3360, 1997 ©The American Society of Hematology 1997
CW1	SOIGNET et al., "Complete Remission after Treatment of Acute Promyelocytic Leukemia with Arsenic Trioxide", J of Medicine 339:19, 1998. ©Massachusetts Medical Society 1998
CX1	TRELEAVEN et al., "Arsenic and Ayurveda", Leukemia and Lymphoma, 10:343-345, 1993
CY1	USP Dictionary of USAN and International Drug Names, United States Pharmacopeial Conventions, Inc., Rockville, MD p. 59, Nov. 1994.
CZ1	WANG et al., "Studies on Chemically Preventing Leukemia", Ghung Hua Chung Liu Tsa Chih, 11(3):207-210, 1989
CA2	XIANG et al., "60 Cases of Treating Acute Promyelocytic Leukemia by QINGDAI Tablet", Med. J. Chin. PLA 20(3):227-229, 1995

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Sheet	4	of	5		

CB2	YUAN et al., "Research on Traditional Methods for Purifying Realgar", Chung Yao Tung Pao, 13(8):23-26, 1988	
CC2	YUAN et al., "Exploring Methods for Purifying Realgar", Chung Yao Tung Pao, 13(8):17-21, 1988	
CD2	ZHANG et al., "Traditional Chinese and Western Medicine in the Treatment of 27 Patients with Malignant Lymphoma," Chinese J. Oncology, 10:61-62, 1988	
CE2	ZHANG et al., "Treatment of Acute Promyelocytic Leukemia with "713": Clinical Observations and Study of Action Mode on 117 patients", J. Harbin Medical Univ. 29(3):243, 1995	
CF2	ZHANG et al., "Treatment of Acute Promyelocytic Leukemia with Intravenous Arsenic Trioxide", Chinese J. of Hematology 17(2) 1996	
CG2	ZHU et al., "Arsenic-induced PML Targeting Onto Nuclear Bodies: implications for the treatment of acute promyelocytic leukemia", Proc. Natl. Acad. Sci. 94:3978-3983, 1997, ©The National Academy of Sciences of the USA 1997	
CH2	"Letter on Historical Facts Regarding the Development of Ai Ling No. 1 and the Clinical Use of Arsenic Trioxide in the Treatment of Acute Promyelocytic Leukemia and a Study of It Mechanism", Heilongjiang Branch of the Chinese Medical Association, Mar. 27, 1998.	
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CK2	WANG et al., "Arsenic and the Treatment of Leukemia", J Harbin Medical Univ., vol. 31, No. 5, Oct. 1997	
CL2	SMORENBURG et al., "Randomized Cross-Over Evaluation of Body-Surface Area-Based Dosing Versus Flat-Fixed Dosing of Paclitaxel", J. Clin. Oncology, 21:197-202 (2003)	
CM2	VOISEN et al., "Extrapolation of Animal Toxicity to Humans: Interspecies Comparisons in Drug Development", Regulatory Toxicology and Pharmacology, 12:107-116 (1990)	
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CO2	GURNEY, "How to Calculate the Dose of Chemotherapy", Brit. J. Cancer, 86:1297-1302 (2001)	
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CQ2	AU et al., "Arsenic Trioxide in Comparison with Chemotherapy and Bone Marrow Transplantation for the Treatment of Relapsed Acute Promyelocytic Leukaemia", Annals of Oncology, 14:752-757 (2003)	
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CS2	WESTERVELT et al.; "Sudden Death Among Patients with Acute Promyelocytic Leukemia Treated with Arsenic Trioxide"; Blood (2001); vol. 98, No. 2, pp. 266-271.	
CT2	SOIGNET et al.; "United States Multicenter Study of Arsenic Trioxide in Relapsed Acute Promyelocytic Leukemia", Journal of Clinical Oncology, (2001), vol. 19, No. 18, pp. 3852-3880	
CU2	WESERVELT et al., "Response and Toxicity Associated with Dose Escalation of Arsenic Trioxide in the Treatment of Resistant Acute Promyelocytic Leukemia", Blood 90 (10) (1997), p. 2496	
CV2	SOIGNET et al., "Initial Clinical Study of a Novel Organic Arsenical, Melarsoprol, in Patients with Advanced Leukemia", Blood (W.B., Saunders, Philadelphia, PA), vol. 88, No. 10, p. 219A (ISSN: 0006-4971) (1996)	

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